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environmental restoration project

**A Department of Energy
Environmental Cleanup Program**

Environmental Restoration Project
Quality Procedure

for:

Standard Operating Procedure Development

Los Alamos
NATIONAL LABORATORY

Los Alamos, New Mexico 87545

Revision Log

Revision No.	Effective Date	Prepared By	Description of Changes	Affected Pages
R0	03/5/98	Larry Maassen	New Procedure. Replaces AP-01.2 and AP-01.5	All
R1	08/27/98	Larry Maassen	Format and process changes	All
R2	02/19/99	John L. Day	Format and process changes	All
R3	05/09/01	Andrew E. Gallegos	Revised to incorporate a revision log page, section 2.0 Scope, Section 3.0 Reference, , new sections to address responsible personnel, Interim Change Notices, lessons learned, PAAA and ISM requirements and periodic procedure reviews	All

Standard Operating Procedure Development

Table of Contents

Standard Operating Procedure Development

1.0 PURPOSE

This Quality Procedure (QP) states the responsibilities and describes the format of and process for preparing, reviewing, approving, revising, and deleting the ER Project's Standard Operating Procedures (SOPs).

2.0 SCOPE

This QP is a mandatory document and shall be implemented by all ER Project participants when developing, maintaining, reviewing or requesting changes to SOPs for the ER Project.

3.0 REFERENCES

3.1 ER Project personnel should become familiar with the contents of the following documents to properly implement this QP.

- ER Project Quality Management Plan located at http://erinternal.lanl.gov/home_links/Library_proc.htm
- QP-2.2, Personnel Orientation and Training
- QP-3.2, Lessons Learned
- QP-3.5, Peer Review Process
- QP-4.2, Standard Operating Procedures Development
- QP-4.4, Record Transmittal to the Records Processing Facility
- QP-4.5, Document Control
- QP-4.9, Document Development and Approval Process: Peer Review Required
- QP-5.7, Notebook Documentation for Environmental Restoration Technical Activities
- Los Alamos National Laboratory Integrated Safety Management Description Document, #LAUR-98-2837
- Price Anderson Amendments Act

4.0 DEFINITION

4.1 *Effective date* — The first date that a particular revision of a document is to be used to perform work. The Document Control Coordinator (DCC) enters it on the cover page and the revision log page, before issuance.

4.2 *Interim Change Notice* — A method of revising a SOP to meet current work processes and/or requirements where the changes are typically of a more narrow scope than a complete revision. An interim change notice is reviewed only by those affected by the change.

4.3 *Major revisions* — Changes to a procedure that affect the technical content or process of the work.

4.4 *Minor revisions* — Editorial changes to a procedure (e.g., grammar or spelling corrections, renumbering sections or attachments, changing the title or document number, or updating organizational changes, etc.) that do not affect the technical content or process of the work.

4.5 *Standard operating procedure* — A document that describes operations, analyses, or actions that are the commonly accepted method for performing certain routine or repetitive tasks (i.e., generally field-implemented procedures associated with the collection of data).

5.0 RESPONSIBLE PERSONNEL

The following personnel are responsible for activities identified in Section 6.0 of this procedure.

5.1 Quality Program Project Leader (QPPL)

5.2 Focus Area Leader

5.3 ER Project Web Master

5.4 Document Control Coordinator

5.5 Author — The technical expert who owns the process described within the SOP. The author may delegate the writing of the SOP to another individual, but retains the ultimate responsibility for the SOP's technical content.

5.6 Requester of an SOP action — Anyone on the ER Project who requests the development of a new SOP, revision of an existing SOP, or deletion of an existing SOP.

5.7 Reviewers

5.8 SOP user

5.9 ER Project Participants

6.0   PROCEDURE

Note: Subcontractors performing work under the ER Project's quality program may follow this quality procedure (QP) for developing standard operating procedures or may use their own procedure(s) as long as the substitute meets the requirements prescribed by the ER Project Quality Management Plan, and is approved by the ER Project's Quality Program Project Leader (QPPL) before the commencement of the designated activities.

Note: ER Project participants may produce paper copies of this procedure printed from the controlled-document electronic file located at http://erinternal.lanl.gov/home_links/Library_proc.htm. However, it is their responsibility to ensure that they are trained to and utilizing the current version of this procedure. The author may be contacted if text is unclear.

6.1   Prior to SOP development and/or revision the **author** shall review the Los Alamos National Laboratory Integrated Safety Management Description Document, #LAUR-98-2837 (located at http://www.lanl.gov/orgs/ism/pdfs/desc_doc.pdf), and the Price Anderson Amendments Act, (located at http://aea.genlaw.lanl.gov/PAAA/index.html) to ensure applicable quality and safety requirements are addressed in the QP.

6.2   SOP Actions Request

6.2.1   The **requester** notifies the QPPL to request a SOP action (i.e., development of a new SOP, revision of an existing SOP, or deletion of an existing SOP).

Note: Any ER Project participant may request a SOP action. The request may be in the form of e-mail or phone call.

6.2.2   If the requested action is a minor revision to an existing SOP, proceed to Section 6.3.

6.2.3   If the requested action is a major revision to an existing SOP or a development of a new SOP, proceed to Section 6.4.

6.2.4   If the requested action is a SOP deletion, proceed to Section 6.9.

6.3   Minor Revisions to Existing SOPs

6.3.1   The **QPPL** or **author** revises the SOP to incorporate the minor revisions (as defined in Section 6.4) and increments the revision number by one whole integer.

6.3.2   The **QPPL** or **author** sends both a hard copy and an electronic copy of the revised SOP to the DCC.

6.3.3 The **DCC** processes the revised SOP in accordance with QP-4.5, Document Control and completes the process as defined in Section 6.8.

6.4 Major Revisions to Existing SOPs or SOP Development

6.4.1 The **QPPL** or the responsible **Focus Area Leader** assigns an author.

6.4.2 For the development of a new SOP, the **author** contacts the DCC to obtain a unique identifier (e. g., ER-SOP-15.01).

Note: An existing SOP will already have an identifier.

6.4.3 The **author** acquires a Document Catalog Number (in accordance with QP-4.9), and fills out the required/associated fields on an ER Project Document Signature Form from (located on the ER Project internal homepage http://erinternal.lanl.gov). The **author** prints out the form and enters the names of the required signatories in the appropriate blocks.

6.4.4 The **author** develops a draft of the SOP that follows the format of the SOP template (located at http://erinternal.lanl.gov/home_links/Library_proc.htm) and as described in Section 6.6, and including the following:

- It must include nine sections numbered 1.0 – 10.0 with the titles described in Section 6.5. The content of each numbered section is also outlined in that section.

- The revision will be "R0" for a new SOP and incremented by one digit for a revision to an existing SOP (e.g., a "R0" would become "R1").

- If forms are used with a SOP, they must also include the SOP identifier.

6.4.5 The **author**, if appropriate, works with an assigned Quality Liaison (or the editor assigned to their focus area if the Quality Liaison is unavailable) to ensure that the SOP is readable, coherent, and adheres to ER Project and Laboratory document-publication guidelines.

6.5 Interim Change Notice

6.5.1 Prior to initiating an Interim Change Notice (ICN), the **requestor** shall confirm with the SOP author and/or the responsible Focus Area Leader to determine if an ICN is appropriate.

6.5.2 The **requestor** acquires and completes a Document Catalog Number (in accordance with QP-4.9), by initiating the ER Project Document

Signature Form The **requestor** shall ensure that no more then 2 ICNs has been issued against a procedure revision.

6.5.3   The **requestor** shall complete an ICN form (see Attachment A located at http://erinternal.lanl.gov/Quality/forms.htm), which include a justification for the ICN that is consistent with the definition in Section 4.2.

6.5.4   The **requestor** shall obtain a review and concurrence by at least one technical reviewer and the QPPL. The **reviewers** shall consider the changed portion of the procedure and the effects of the changes on the procedure.

6.5.5   After the ICN has been reviewed and approved, the **QPPL** shall forward an electronic and hard copy to the DCC for processing (Proceed to Section 6.8).

6.6   SOP Format

A template for developing SOPs is provided on the ER Project Intranet at http://erinternal.lanl.gov/home_links/Library_proc.htm. This template provides the proper paragraph formatting, text that both demonstrates how the different sections will look and how to properly accomplish the formatting, and the standard text for the notes and introductory paragraphs for the different sections.

6.6.1   Cover Page

Include a cover page, which uses the format of the cover page provided in the SOP template.

6.6.2   Revision Log

Include a revision log page, which lists the revision number and date, author's name, a brief description of the changes, and the affected pages.

6.6.3   Table of Contents

Include a table of contents, which lists Sections 1.0 – 10.0 that are described below.

6.6.4   Pagination

During ER Project Document Signature Form initiation, an automatic ER catalog number is generated within the form. Reference this number in the footer of the document. Also, place the unique identifier ("SOP-X.XX, RN", where "X.XX" is the specific number assigned to the SOP by the DCC and "RN" is the revision number) and page numbers, as appropriate in the footer on all pages of the SOP (including attachments) as follows:

6.6.5   1.0 Purpose

The purpose statement is a brief description of the task or operation whose performance will be governed by the procedure.

6.6.6   2.0 Scope

Include a section that defines the limits of the SOP's applications regarding affected activities and organizations (for clarity, specific exclusions may be stated). This section may also provide instructions for transition to the revised procedure.

6.6.7   3.0 Training

Include a section that lists the training method required for personnel to use this SOP (e.g., reading the procedure, formal classroom training, on-the-job training, etc.).

6.6.8   4.0 Definitions

Include a section that defines the terms that are unique to the SOP or terms that may be unfamiliar to the SOP user. A glossary of definitions can be located on the ER Project internal homepage http://erinternal.lanl.gov.

6.6.9   5.0 Responsible Personnel

Include a section that lists the individuals (by formal ER Project position title when appropriate) who have responsibilities in the SOP.

6.6.10 6.0 Background and Precautions

Provide any background information associated with the activities described in this SOP that may help users to better understand the activities.

Note: This SOP is to be used in conjunction with an approved SSHASP. Also, consult the SSHASP for information on and use of all PPE. **[Include this mandatory note in all fieldwork related SOPs]**

6.6.11 7.0 Equipment

List the equipment and supplies used to perform the procedure. If the equipment is listed on an attachment to the SOP, reference the attachment here. If applicable, specify the correct version of the manufacturer's operating manual that is to be used with the equipment and ensure that it is available for use.

6.6.12 8.0 Procedure

Note: Deviations from SOPs are made in accordance with QP-4.2, Standard Operating Procedure Development, and QP-5.7, Notebook Documentation for Environmental Restoration Technical Activities. **[Include this mandatory statement in all procedures]**

Include a section that briefly states the required work in clear and concise steps, giving one step per each numbered subsection, including calibration of equipment, quality control hold and witness points, and acceptance criteria. Also describe applicable quality assurance and quality control management tools that are unique to the SOP. Where applicable, reference existing documents (e.g., ER-SOP-01.05, Field Quality Control Samples) that are used to demonstrate quality or control. Identify the person (from Section 5.0, above) who performs each step. In addition, the following mandatory notes shall be included in all procedures at the beginning of Section 8.0:

Note: Subcontractors performing work under the ER Project's quality program may follow this standard operating procedure (SOP) for *[insert this document's subject area here]* or may use their own procedure(s) as long as the substitute meets the requirements prescribed by the ER Project Quality Management Plan, and is approved by the ER Project's Quality Program Project Leader (QPPL) before the commencement of the designated activities.

Note: ER Project participants may produce paper copies of this procedure printed from the controlled-document electronic file located at http://erinternal.lanl.gov/home_links/Library_proc.htm. However, it is their responsibility to ensure that they are trained to and utilizing the current version of this procedure. The author may be contacted if text is unclear.

6.6.13 9.0 References

Include a section that lists, by document number and title, the references cited in Sections 4.0 through 11.0. This section shall also include the following:

- ER Project personnel should become familiar with the contents of the following documents to properly implement this QP. **[Include this mandatory statement in all procedures]**

6.6.14 10.0 Records

Include a section that states who is responsible for record submittal and list the records that are generated by the SOP.

6.6.15 11.0 Attachments

Include a section that lists attachments that are part of the SOP. List the attachment identifier (e.g., Attachment A), title (e.g., "Reviewer Concurrence Form"), and number of pages for each attachment. Follow the format shown below.

Attachment A: Attachment Title (1 page)

6.7 SOP Peer Reviews

6.7.1 The **author** ensures that the SOP (except for minor revisions to an existing SOP) is reviewed and approved in accordance with QP-03.05, Peer Review Process.

6.7.2 When satisfied that the SOP is ready for approval, the **author** shall acquire the required signatures on this ER Project Document Signature Form in accordance with QP-04.09.

6.7.3 When all signatures have been acquired, the **QPPL** shall submit an electronic and hard copy of the approved SOP and ICN, as appropriate to the DCC

6.8 Issuing SOPs

6.8.1 After completing step 6.7.3, the **DCC** enters the effective date on the SOP cover page and in the appropriate block in the records log page and provides a PDF electronic copy of the SOP and ICN, as appropriate to the ER Project Web Master.

6.8.2 The **DCC** shall make the ER Project Web Master aware of all web links and forms as noted within the procedure.

6.8.3 The **ER Project Web Master** shall activate all links and forms as noted within the procedure and include all submitted ICNs as a cover page for the affect procedures. After completion of this process, the **ER Project Web Master** shall then notify the QPPL that the SOP has been placed on the ER Project web page.

6.8.4 The **QPPL** shall then notify all ER Project participants of the issuance of a newly revised/developed SOP.

6.8.5 The **DCC** processes the SOP in accordance with QP-04.05, Document Control.

6.9 Deleting SOPs

6.9.1 To determine whether or not a SOP is still needed, the **QPPL** informally notifies (e.g., by email or telephone) SOP users when a SOP deletion is requested.

6.9.2 The **QPPL** notifies the DCC to delete the SOP, unless notified by a user that the SOP is still needed

6.9.3 The **DCC** processes the deleted SOP in accordance with QP-4.5, Document Control.

6.10 Deviations to SOPs

Uniqueness of field conditions may require temporary deviations from the SOP as written. Deviations are processed as follows.

6.10.1 The **SOP user** documents the description of and purpose for the deviation to the SOP in a field logbook or notebook in accordance with QP-05.07, Documentation of Environmental Restoration Technical Investigations.

6.10.2 The **SOP user** documents whether the deviation is a one-time event or one that requires a revision to the SOP (e.g., due to an error in the SOP).

6.10.3 The **SOP user** forwards a copy of the deviation to the QPPL and, if the deviation requires a revision to the SOP, a request to have the SOP revised is submitted to the author.

6.10.4 If necessary, the **QPPL** processes a SOP revision in accordance with QP-4.2, Standard Operating Procedure Development.

6.11 Periodic SOP Reviews

The **author** or the **Focus Area Leader** shall if appropriate review all SOPs within their purview at least every two years to ensure that they meet the following criteria:

- current methods and/or processes;

- current regulations, standards, laws, and/or requirements;

- addition and/or deletion of required equipment; and

- current procedural format or required work processes.

6.11.1 Should the SOP require revision the **author** or the **Focus Area Leader** will revise the SOP by following the requirements addressed in this QP.

6.12 Perform Lessons Learned

During the performance of work, **ER Project participants** shall identify, document and submit lessons learned, as appropriate in accordance with QP-3.2, Lessons Learned, located http://erinternal.lanl.gov/home_lings/Library_proc.htm.

7.0 RECORDS

The **author** is responsible for submitting the following records (processed in accordance with QP-4.4, Record Transmittal to the Records Processing Facility) to the Records Processing Facility.

7.1 A copy of the SOP approved for issuance

7.2 A signed copy of the ER Project Document Signature Form

7.3 A signed copy of the Interim Change Notice, if appropriate

7.4 An Electronic copy of the approved SOP

7.5 Correspondence addressing periodic reviews of the SOP

8.0 TRAINING

8.1 All users of this QP are trained by reading the procedure. The **user** shall ensure the training is documented in accordance with QP-2.2, Personnel Orientation and Training, and is entered in the ER Project Training Database located at http://erinternal.lanl.gov/Training/Training.asp.

8.2 The **supervisor** will monitor the proper implementation of this procedure and ensure that relevant team members have completed all applicable training assignments in accordance with QP-2.2, Personnel Orientation and Training.

9.0 ATTACHMENTS

Attachment A: SOP Interim Change Notice form (1 page), located at http://erinternal.lanl.gov/Quality/user/forms.asp.

Attachment B: SOP Interim Change Notice Instructions (1 page)

Standard Operating Procedure Interim Change Notice

Section 1: Description of Change (Requestor completes)	1. Document Catalog No.:

2. SOP No.:	3. Revision/Interim Change No.: (current)	4. SOP Title:

5. Description of Change (Attach marked-up pages if necessary)

6. Attachments Modified, Added, or Removed:　　　　☐ Yes　　　　☐ No

7. Justification for ICN:

8. Requestor _____

　　　　　　(print name, then sign)　　　　　　　　　　　　　　　　　　(Date)

Section 2: Evaluation and Approval (QPPL and the Focus Area Leader completes)

9. Evaluation Remarks: (If none enter N/A)

10. Focus Area Leader _____

　　　　　　　　(print name, then sign)　　　　　　　　　　　　　　(Date)

11. QPPL _____

　　　　(print name, then sign)　　　　　　　　　　　　　　　　(Date)

QP-4.2	Los Alamos Environmental Restoration Project

Instructions for SOP Interim Change Notice (ICN)

Section 1 – Description of Change (Requestor Completes)

1. Enter the document catalog number.

2. Record the procedure number.

3. Record the current revision and interim change number, as applicable (The Document Catalog Number shall be used as the ICN). The Document Catalog Number is obtained in accordance with QP-4.9, and is located on the ER Project internal homepage http://erinternal.lanl.gov.

4. Record the procedure title.

5. Describe the change. Provide marked-up copies of the procedure or attach additional sheets, as necessary.

6. Identify whether procedure attachments were modified, added, or removed. If "yes", identify the affected attachments.

7. Provide a clear and concise justification for the interim change notice.

8. Enter a printed and signed signature and date.

Section 2 – Evaluation and Approval (QPPL and Focus Area Leader Completes)

9. Record any evaluation remarks; If none, enter N/A.

10. Record the name of the responsible Focus Area Leader, sign and date.

11. Record the name of the QPPL, sign and date.